Claims 1-36 are all the pending claims. By this Amendment, claims 1-36 have been amended to recite clear and definite language under U.S. practice, and claims 25 and 27-29 have been amended into independent claims and to incorporate the subject matter of the claims from they originally depended.

No new matter has been added, and consideration and entry of the amended claims is requested.

I. Response to Objection to Specification

The specification has been amended pursuant to 37 CFR §1.77(b) and the Examiner's objection is accordingly rendered moot.

II. Response to Rejection of Claims 2, 3 and 5-36 under 35 U.S.C. §112, second paragraph

Claims 2, 3 and 5-36 are rejected under the second paragraph of §112 for indefiniteness.

Applicants' reply to the Examiner's rejection for each of the claims is set forth below in the order in which they appear in the Office Action.

A. Claim 2 recites "wherein has".

The deletion of the phrase from Claim 2 renders this aspect of the Examiner's rejection moot.

B. In Claim 3, there is no antecedent basis for the phrase "the upper anterior part", and numerals referencing elements in Figures should be in parentheses.

The deletion of both the phrase and the numeral from claim 3 renders the Examiner's rejection moot with respect to this aspect of his rejection.

C. Claim 5 recites "chosen in".

The deletion of the phrase from Claim 5 renders this aspect of the Examiner's rejection moot.

D. Claim 6 recites "such as bumps and recesses".

"Such as" has been replaced with the term "comprising".

E. Claim 7 is rejected for reciting "a flat, developed shape" when Claim 1 recites the preform having a three-dimensional structure.

The phrase "a flat, developed shape" corresponds to the structure described in the paragraph bridging page 7, line 24 to page 8, line 14 of the specification. The preform itself has a "three-dimensional hollow body", but can be constructed starting from a flat shape.

F. Claims 8 and 24 recite "Bonnets Nighttime Lingual Envelope or N.L.E.", which according to the Examiner, is an unknown devise in the field of dentistry, and which is not further defined by the specification.

Applicants submit that the Bonnets' Nighttime Lingual Envelope (NLE) was developed after the publication date (1982) of the Dictionary cited by the Examiner in the Office Action.

To facilitate the Examiner's understanding of the meaning for NLE, Applicants are enclosing copies of two technical articles (Annexes A and B) describing this orthodontic device and its therapeutic use, which is based on the positioning of the tongue.

As regards the differences between the preform and the NLE apparatus, Applicants are also enclosing an illustration (Annex C) representing a preform prior to expansion and an NLE after expansion and the finishing steps, i.e., a finished product for oral use in a subject. The picture illustrates that a preform requires that the object undergo structural transformations prior to its intended use (e.g., modification of the preform to allow a perfect adaptation to the subjects morphology and the positioning of the hooks; see, for example, page 8, lines 15-27 or page 11, lines 24-30).

Additionally, in view of claim 8 now being directed to a Bonnet's Nighttime Lingual Envelope (NLE) comprising the preform of claim 1, Applicants have obviated this aspect of the Examiner's rejection.

G. Claim 9 is unclear as to 1) whether the term "contains" is to be deleted; 2) recites "his patient" rather than "a patient"; and 3) whether a finishing step is being claimed.

Claim 9 has been amended to recite clear and definite language and the intended process steps for this invention which renders this aspect of the Examiner's rejection moot.

H. The comma in Claim 10 is unnecessary.

The comma has been deleted from Claim 10.

I. The Examiner is not able to discern the meaning of Claim 13.

Claim 13 is drawn to the expanding step of c) and includes a recital for any method which effectuates an expanding of the preform.

J. The comma in Claim 18 is unnecessary.

The comma has been deleted from Claim 18.

K. Claim 20 recites "insertion by duplicate molding".

That portion of the phrase "by duplicate molding" has been deleted from Claim 20.

L. Claim 22 recites "movable anchoring joints".

Claim 22 has been amended to depend from claim 21 and is directed to a finishing step of d) comprising anchoring the fastening hooks to moveable anchoring points. "Moveable anchoring points" constitute particular means for fixing the apparatus in the mouth which has the advantage of being moveable if the therapeutic treatment requires that the apparatus be adjusted in a different way for fitting into the mouth (see, for example, page 17, line 30 to page 20, line 2).

The claim is correctly dependent with respect to the claimed subject matter.

M. Claim 23 recites "preceding cycle" for which there is no antecedent basis.

Claim 23 has been amended to recite "the process of a preceding cycle". The phrase finds support on page 17 at lines 25-33 where it is disclosed that an apparatus can be used several times in the process as set forth in claim 9. An aspect of the invention is that an apparatus be adapted for changes in morphology, and the expansion step of c) is designed so that the apparatus is specifically configured to the morphology of the subject. Therefore, the term "preceding cycle" means the succession of stages in the process of claim 9 performed to obtain the dento-facial or orthopedic device.

N. Claims 25-31 and 36 rejected for improper dependency.

Claims 25 and 27-29 have been amended to incorporate the subject matter of the claims from which they originally depended. Claims 26, 30-32 and 36, which depend from one of claims 25 or 27-29, are now properly dependent.

O. Claim 25 is an improper single means claim.

Claim 25 recites that the expansion controlling means of step c) is for obtaining an apparatus having a desired shape. Applicants submit that the claim is now a proper means-plus-function claim.

P. Claim 26 recites underlined words within bracketed text and describes a method for an apparatus.

Claim 26 has been amended to recite "the means for controlling expansion" of the extension core, and no reference to a method can be found in the claim.

Q. Claim 28 recites a "fastening hook" but no further reference to the fastening hook is made in the claim; a bent-back segment is unclear; and "the apparatus" and "the end of insertion" lack antecedent basis.

Applicants submit that instant claim 28 finds full support on page 20 at lines 14-23 of the specification and in Figure 10 as originally filed. As stated on page 21 at lines 10-18, Figure 10 represents a hook with a bent back segment inserted into an apparatus. For further clarification, Applicants are enclosing an illustration (Annex D) of the apparatus having a bent-back segment and the attached fastening hook which is adapted for insertion into the apparatus.

R. Claim 29 does not provide sufficient structural definition for the device.

Instant claim 29 recites that the device has means for providing electrical heating energy and stable mechanical positioning of the hook for anchoring to the apparatus.

S. Claim 30 is unclear for reciting 1) "mechanism"; 2) what is being added or deleted; and 3) "a technician's hands" as part of the invention.

Instant Claim 30 recites the intended subject matter in clear and definite language.

T. Claim 31 is unclear for reciting 1) "mechanism"; 2) lack of antecedent basis for "the stable mechanism" and "the ends"; and 3) the "for example" limitation.

Applicants submit that the phrase "the stable mechanism" finds support in the Claim 29 from which claim 31 depends. With respect to "the ends", the claim recites "distal ends", and the "for example" limitation has been deleted.

U. Claim 32 does not recite to what the fastening hooks are attached.

Claim 22 recites that the fastening hooks are attached to the apparatus, and since claim 32 depends from claim 22, claim 32 is definite.

V. Claim 33 claims an apparatus without defined structure.

The apparatus of claim 33 is defined by the structure for the preform since the apparatus is comprised of the preform of claim 1, making the claimed subject matter definite.

W. Claim 33 claims an apparatus having the properties of NLE which are undefined.

Please refer to Applicants' comments under section F and the attached annexes A and B for the meaning of NLE.

X. Claim 35 recites "material registrant".

Claim 35 now recites "material resistant".

Y. Claim 36 recites "mechanism" and a "gun" for fastening hooks.

Claim 36 now recites a "device" and is directed to the device being a gun.

III. Response to Rejection of Claim 25 under 35 U.S.C. §112, first paragraph

Claim 25 is rejected under 35 U.S.C. §112, first paragraph, for lack of enablement.

The Examiner has rejected Claim 25 as being an improper single means claim.

Applicants traverse and submit that Claim 25 recites that the expansion controlling means of the extension core of step c) is for obtaining an apparatus having a desired shape. Applicants submit that the claim is now a proper means-plus-function claim.

IV. Response to Improper Dependent Claim Format

Claims 25-31, 33, 34 and 35 are objected to under 37 CFR 1.75 for improper dependent claim format.

Applicants have rewritten the claims to include all of the limitations of the claims from which they depend, and submit that the rejection is obviated.

V. Response to Rejection of Claims 1-8 under 35 U.S.C. §102(b)

Claims 1-8 are rejected under 35 U.S.C. §102(b) for being anticipated by Nilsson (USPN 4,391,861).

According to the Examiner, claims 1-8 are anticipated by Nilsson since the reference discloses a hollow thermoplastic preform for blow molding, and none of Applicants claimed structural distinctions imposes patentability upon the preform.

Applicants traverse and submit that claims 1-8 are novel over Nilsson.

Pursuant to MPEP § 2111.02, the preamble must be given patentable weight in order to point out the invention defined by the claim and in order to limit the claim. In the present case, claim 1 recites "a preform for obtaining a personalized orthopedic or dento-facial othorpedic apparatus." Thus, the preamble teaches some of the intrinsic characteristics of the preform, regarding its overall size and its being made of a biocompatible material.

Nilsson is related to preforms suitable for the manufacture of containers conforming to specific requirements with respect to dimensional stability, gas penetration, and light penetration (see col. 2, lines 34-50). The preform of Nilsson could not be adapted to replace or substitute the instant claimed preform in order to obtain an orthodontic apparatus.

Moreover, the preform of Nilsson is adapted to first undergo axial stretching, followed by traverse stretching (see col. 5, lines 40-46) during molding, but not multidirectional stretching. If a preform of Nilsson were exposed to the claimed expansion, it would tear as a result of the stretching required for

the material to conform to the walls of the plaster model. In other words, a preform with a revolution axis and constant thickness could not be used to obtain an orthodontic apparatus in conformity with the requirements regarding the rules of the art in the orthodontic field. See page 7, lines 17-23; page 10, lines 19-25; and page 11, lines 27-30 which explains these requirements.

In view of the foregoing comments, Applicants submit that the instant claimed preform does not read on the preform of Nilsson, and therefore, claims 1-8 are not anticipated.

VI. Response to Rejection of Claims 8, 33 and 34 under 35 U.S.C. §102(b)

Claims 8, 33 and 34 are rejected under 35 U.S.C. §102(b) for being anticipated by Bonnet's Nighttime Lingual Envelope.

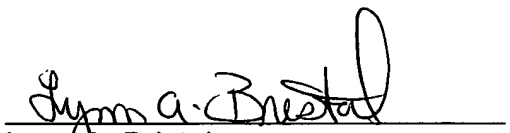
Even assuming, *arguendo*, that a Bonnet's Nighttime Lingual Envelope is an already known apparatus, Applicants submit that the prior art does not teach or suggest that the instant claimed preform could be used to form any such apparatus. Creating an apparatus such as that resembling a Bonnet's Nighttime Lingual Envelope with the instant claimed preform is not inherent to the apparatus nor disclosed in the prior art. Accordingly, withdrawal of this rejection is deemed proper.

CONCLUSION

In view of instant claims 1-36 and Applicants' foregoing comments, Applicants submit that rejections raised by the Examiner under 35 U.S.C. §102(b), and the first and second paragraph of §112 have been met and overcome. Applicants submit the claims are now in condition for allowance, and request that the Examiner find the present application allowable and that it be passed to issuance.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300.

Respectfully submitted,



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MARKED UP COPY OF CLAIMS

1. (Twice Amended)A preform [allowing] for [the obtainment] obtaining, after deformation, a personalized orthodontic [of] or dentofacial orthopedic apparatus characterized by a three-dimensional hollow body which has a form that allows the preform's expansion inside a mold reproducing [the] a morphology of [the patient] a subject.

2. (Twice Amended) The preform according to claim 1, [wherein has] comprising a hollow tubular or approximately tubular shape.

3. (Twice Amended) The preform according to claim 1, characterized by a hollow, tubular or approximately tubular shape and [is] being cut [on the upper anterior part] to form an opening [8].

4. (Twice Amended) The preform according to claim 1, [characterized by the fact that it is manufactured in] comprising a thermoplastic or thermosetting plastic material which is deformable through expansion.

5. (Twice Amended) The preform according to claim 4, [characterized by the fact that it is manufactured using] comprising a thermoplastic [plastic] material [chosen in the group constituted] selected from the group consisting of polyethylene, polypropylene, polycarbonate, methyl

polymethacrylate, PVC, and [polyurethanes] polyurethane, or [using] a thermosetting plastic material [chosen in the group constituted by] selected from the group consisting of methyl polymethacrylate and [polyurethanes] polyurethane.

6. (Twice Amended) The preform according to claim 1, characterized by a surface with guides [such as] comprising bumps or recesses intended to guide [the] a technician during cutting operations and/or initial holes [(7) that are used to hold the] for holding fastening hooks of [the finished] the dentofacial [appliance] apparatus.

7. (Twice Amended)The preform according to claim 1, [characterized by the fact that it is manufactured in] comprising a flat, developed shape prior to [being given shape] shaping by a technician.

8. (Twice Amended) The preform according to claim 1, yielding after deformation, a Bonnet's Nighttime Lingual Envelope [or N.L.E].

9. (Twice Amended) A process for [the production of] manufacturing a personalized orthodontic or dento-facial orthopedic apparatus, [the following] comprising [steps]:

[-] a) [comprising creation of] providing a female mold [(9, 10)] based at least in part on study models created by a practitioner from [the] a casting or castings made from [his patient] a subject,

[-] b) positioning [the] a preform [(1)] of claim 1 in the female mold,

[-] c) [expansion of] expanding the preform [until it has reached the] to obtain the apparatus having a desired shape, and

[-] d) [ejection from the mold of the obtained apparatus which becomes functional after finishing] removing the apparatus from the mold and finishing the apparatus.

10. (Twice Amended) The process according to claim 9, [characterized by the fact that the expansion] wherein the expanding step of c) is preformed with heat and [that] the preform is brought to [the] a deformation temperature of its constitutive material prior to[the] expansion [stage,].

11. (Twice Amended) The process according to claim 10, [characterized by the fact that the expansion] wherein an expansion temperature is attained by [the action of] radiation or a heat bearing fluid.

12. (Twice Amended) The process according to claim 11, [characterized in that] wherein the radiation [used] is [of the] microwave, [or] ultraviolet or infrared [type].

13. (Twice Amended) The process according to claim 9, [characterized by the fact that] wherein the [expansion] expanding step of c) is performed by [any appropriate] a method [to obtain the] for obtaining an expansion of the preform to [the] a desired shape.

14. (Twice Amended) The process according to claim 13, [characterized by the fact that the expansion is preformed] comprising expanding by [the action of] an expansion fluid or mechanically.

15. (Twice Amended) The process according to claim 14, [characterized by the fact that] wherein the expansion fluid is compressed air or water.

16. (Twice Amended) The process according to claim 9, [characterized by the fact that the expansion] wherein the expanding step of c) [takes place through the intermediary of] occurs by inserting an expansion core [(14) placed] in the preform [(1)] and [inflated by] inflating the expansion core with [the] an expansion fluid.

17. (Twice Amended) The process according to claim 16, [characterized in that] wherein the expansion core is a controlled expansion core [(16)].

18. (Twice Amended) [Process] The process according to claim 16, [characterized by an] wherein the expansion core [(14, 16) made of] comprises a material resistant to [the] an expansion temperature.

19. (Twice Amended) [Process] The process according to claim 9, [characterized by the fact that] wherein the preform is made of thermosetting material and [in that the expansion stage] the expanding step of c) is simultaneously or later accompanied by a step for polymerization of the thermosetting material.

20. (Twice Amended) The process according to claim 9, [characterized by the fact that it] further [comprises, insertion] comprising inserting [by duplicate molding, of] fastening pieces or additional pieces during [expansion] the expanding step of c).

21. (Twice Amended) The process according to claim 9, [characterized by the fact that] wherein the finishing step of [step] d) includes at least one of [the following actions: preparation of] preparing one or more openings, polishing, anchoring of fastening hooks, setting of additional pieces, elimination of useless parts, or reduction of [the] surface [in certain] areas.

22. (Twice Amended) The process according to claim [9] 21, [characterized by the fact that it includes a] wherein the finishing step of d)

comprises [for] anchoring the fastening hooks [in] to moveable [to] anchoring points on the apparatus.

23. (Twice Amended) The process according to claim 9, [characterized by the fact that] wherein the dento-facial orthopedic or orthodontic [device] apparatus obtained by the process [in the] of a preceding cycle, is used as [a] the preform.

24. (Twice Amended) The process according to claim 9, [characterized by the fact that] wherein the personalized orthodontic or dento-facial orthopedic apparatus [obtained] is a Bonnet's Nighttime Lingual Envelope [or N.L.E].

25. (Twice Amended) An expansion core [appropriate] for [implementation of] a process for manufacturing a personalized orthodontic or dento-facial orthopedic apparatus, comprising:

a) providing a female mold based at least in part on study models created by a practitioner from a casting or castings made from a subject,

b) positioning a preform in the female mold,

c) expanding the preform with the expansion core comprising at least one means of controlling its expansion for obtaining an apparatus having a desired shape, and

d) removing the apparatus from the mold and finishing the apparatus, wherein the preform comprises a three-dimensional hollow body with a form allowing expansion of the preform inside a mold reproducing a morphology of a subject [according to claim 16 and containing at least one means of controlling its expansion].

26. (Twice Amended) [An] The expansion core according to claim 25, [wherein] comprising [the method] means [of] for controlling its expansion [is chosen from among the following methods,] by increasing [an increase in the] thickness of its wall in certain areas [and the introduction in its wall of rigid reinforcements] or introducing rigid reinforcements into its wall.

27. (Twice Amended) An expansion mechanism [appropriate] for [the implementation of] a process for manufacturing a personalized orthodontic or dento-facial orthopedic apparatus, comprising:

a) providing a female mold based at least in part on study models created by a practitioner from a casting or castings made from a subject,

b) positioning a preform in the female mold,

c) expanding the preform with the expansion mechanism so as to obtain an apparatus having a desired shape by displacement of mechanical pieces on the expansion mechanism, and

d) removing the apparatus from the mold and finishing the apparatus,

wherein the perform comprises a three-dimensional hollow body with a form allowing expansion of the preform inside a mold reproducing a morphology of a subject [according to claim 9 and adapted so that the preform reaches the desired shape by displacement of mechanical pieces changed by the technician during the expansion phase].

28. (Twice Amended) A fastening hook for an orthodontic or dento-facial orthopedic apparatus manufactured according to [the] a process [described in claim 9 based on] comprising

a) providing a female mold based at least in part on study models created by a practitioner from a casting or castings made from a subject,

b) positioning a preform comprising a thermoplastic material in the female mold,

c) expanding the preform so as to obtain an apparatus having a bent-back segment for inserting the fastening hook, and

d) removing the apparatus from the mold and finishing the apparatus,

wherein the fastening hook is inserted into the bent-back segment of the apparatus [a preform made of a thermoplastic plastic material characterized by the fact that it contains a segment called bent-back segment which remains outside the apparatus at the end of insertion].

29. (Twice Amended) A device for attaching a fastening [hooks] hook according to claim 28 [on] to an orthodontic or dento-facial orthopedic apparatus

[manufactured according to the process described in claim 9 characterized by a mechanism for supplying] comprising means for supplying electrical heating energy and stable mechanical positioning of the fastening hook [to be anchored] for anchoring to the apparatus.

30. (Twice Amended) [A mechanism] The device according to claim 29, [characterized by the fact that] wherein the electrical energy is supplied by a hand-held, portable current generator [held by the hand of a technician and] containing two rigid electrical conductors[,].

31. (Twice Amended) [A mechanism] The device according to claim 29, [characterized by the fact that] wherein the stable mechanical positioning is [done] performed with [the] distal ends of electrical conductors [which have] having a clamp shape, and the distal ends are adapted to the diameter of [the] a wire or to [the] a shape of the hook to be inserted[, for example a fork shape].

32. (Twice Amended) [A] The process according to claim 22, [characterized by] wherein the fastening hooks are attached using a fastening mechanism.

33. (Twice Amended) A personalized orthodontic or dento-facial orthopedic apparatus, [characterized by the fact that it is manufactured based on] comprising a preform [(1)] according to claim 1.

34. (Twice Amended) A personalized orthodontic or dento-facial orthopedic apparatus according to claim 33, [characterized by] comprising a Bonnet's Nighttime Lingual Envelope or [N.L.E].

35. (Amended) The process according to claim 18, wherein the material [registrant] resistant to an expansion temperature is an elastomer.

36. (Amended) [A mechanism] The device according to claim 29, [characterized by the fact that] wherein the electrical energy is supplied by a gun that mechanically holds a pair of rigid electrical conductors connected by flexible conductors to a fixed generator.

Bruno BONNET
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Spécialisé qualifié en orthopédie dento-faciale

Annexe A

l'Enveloppe Linguale Nocturne ou ELN de Bonnet

Je remercie la Revue Prothèse Dentaire, qui m'a, par l'intermédiaire d'Eric Hébert, invité à écrire ces quelques lignes sur l'ELN et donc sur la langue. Ceci aboutissant à redonner sa place véritable au patient, et à l'acte thérapeutique que finalement il accomplit au cours de nos traitements orthodontiques et généraux.

En effet, la vraie orthodontie ou la vraie thérapeutique est celle qui est faite par le patient. Prothésistes et chirurgiens-dentistes, n'étant que les aides, les secours, à cet accomplissement par le patient de l'oeuvre essentielle de croissance ou de guérison. Leur intervention n'en est pas moins précise et exigeante. Et cette courte introduction à l'ELN, dans un langage au plus loin du vocabulaire spécialisé, offre une occasion importante de l'exprimer.

ORIGINE DE L'ELN

L'ELN est une petite invention, née de la collaboration de la prothèse dentaire orthodontique en la personne de Jean-Jacques Dejonge, et de la clinique orthodontique en ma personne.

Annexe B

Un appareil de reposturation : l'Enveloppe Linguale Nocturne (E.L.N.)

Bruno BONNET

RÉSUMÉ

Les troubles de la posture et de la fonction linguales sont souvent la conséquence de la conservation d'une proto-motricité « palpatoire ».

L'auteur propose un appareil appelé « Enveloppe linguale nocturne » ou « E.L.N. » pour éduquer la langue vers une motricité « secondaire » qui s'adapte au cadre anatomique précorrigé. La langue devient alors l'appareil orthopédique naturel de la cavité buccale et de la face.

SUMMARY (p. 347)

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MOTS CLÉS

Déglutition primaire – Posture linguale – Education linguale – Physiologie neuro-musculaire.

I – INTRODUCTION

La mise en évidence de programmes moteurs « innés » par la neurophysiologie moderne est au centre d'une réorganisation générale des grandes notions de la physiologie classique.

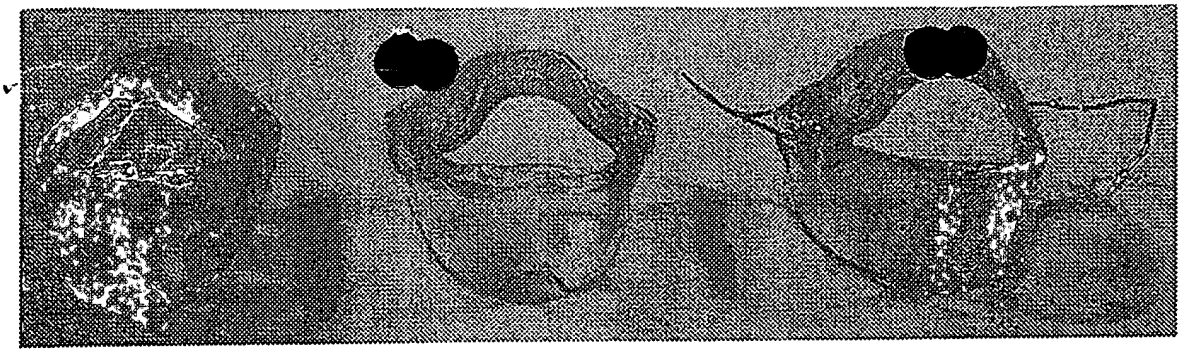
La notion de programme moteur inné central est à saisir au sens informatique du terme.

Nous devons en retenir que ces programmes contiennent en eux-mêmes, dans leur logique câblée, tous les détails de l'organisation spatio-temporelle nécessaires à l'exécution correcte de la fonction, et ceci, *sans aucune assistance sensorielle*, dans des conditions habituelles, donc prévisibles.

Cette notion trouve une articulation nouvelle avec celle *« d'espace de fonctionnement »* définie par la théorie de la matrice fonctionnelle.

La langue devient le véritable agent de la mise en relation des *caractéristiques spatiales* des structures buccales et des *instructions* génétiquement pré-inscrites dans les séquences motrices du programme de déglutition.

Rev Orthop Dento Faciale 26 : 329-347, 1992

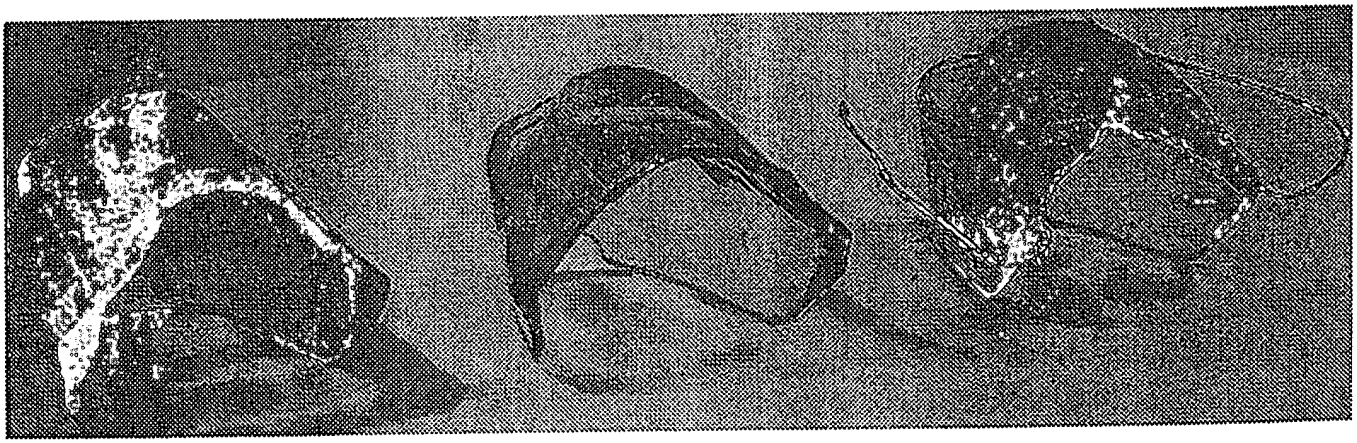


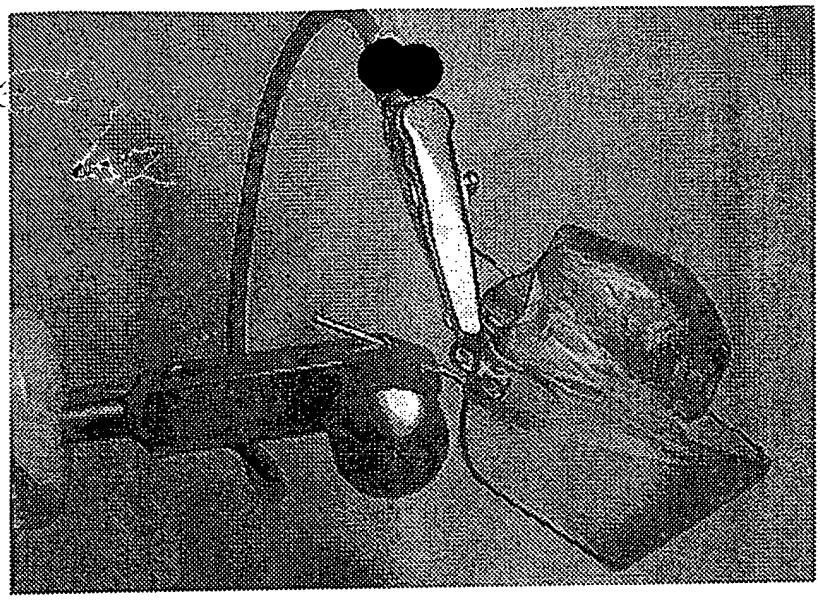
preform of an NLE

preform of an NLE after expansion according to the invention

NLE ready for the settlement in the mouth of a patient (incorporating the fastening hooks)

Annex C





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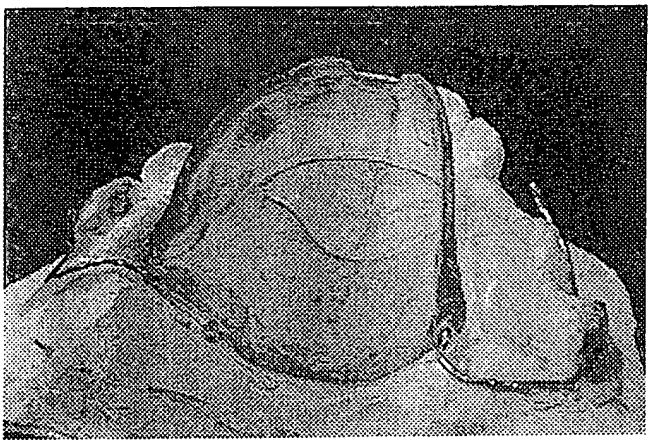

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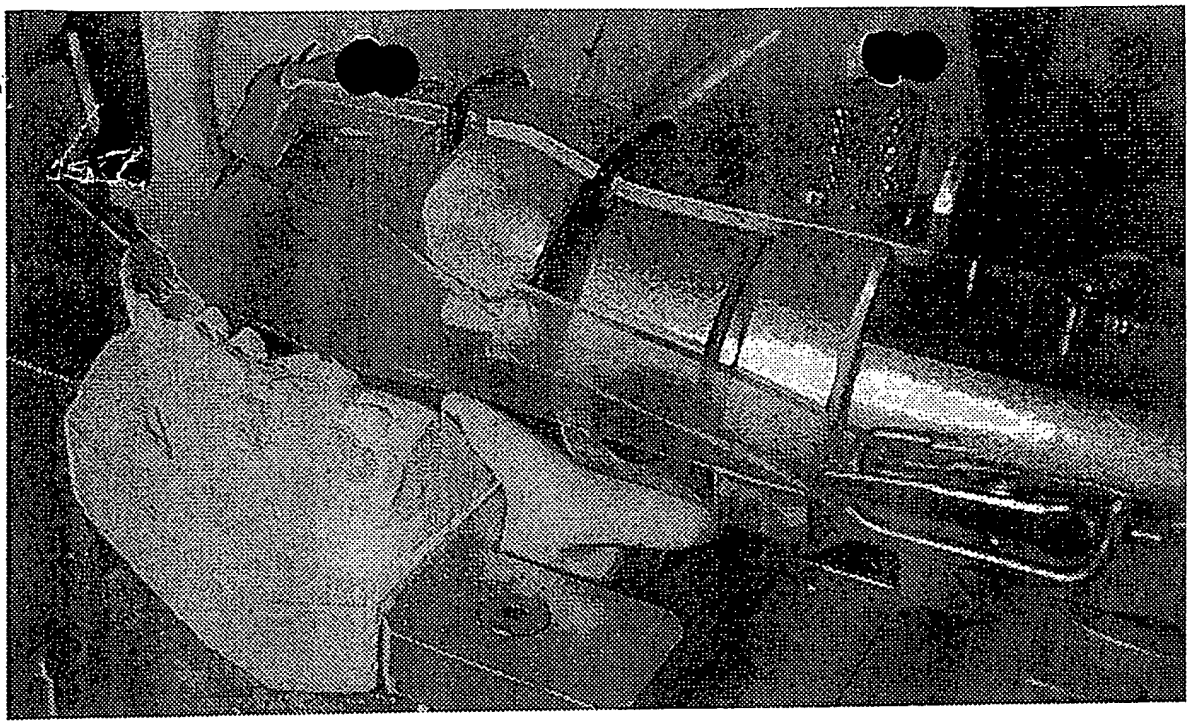

Annex F